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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/483,352	01/21/00	GOUDENIT	1752300-1A

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EXAMINER
SISSON, B

ART UNIT	PAPER NUMBER
1835	5

07/20/00

DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/463,352

Applicant(s)

GOUDSMIT ET AL.

Examiner

Bradley L. Sisson

Art Unit

1655

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- 1) ☒ Responsive to communication(s) filed on 21 January 2000.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some * c) ☒ None of the CERTIFIED copies of the priority documents have been:
1. ☒ received.
 2. ☐ received in Application No. (Series Code / Serial Number) _____.
 3. ☐ received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4.
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____.

DETAILED ACTION

Priority

1. Acknowledgment is made of applicant's claim for foreign priority based on an application filed in EP on 8 August 1997. It is noted, however, that applicant has not filed a certified copy of the PCT/EP98/04945 application as required by 35 U.S.C. 119(b).

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 5-7 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are:

- a. The conditions employed such that only the desired target sequence (HIV RNA) is amplified;
- b. The use and detection of a detectable marker; and
- c. Correlation of the detected amplified nucleic acid to the intended prod size such that a positive assessment for the presence of HIV can be made.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102((e), f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 1-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over McDonough et al., in view of Research Genetics.

McDonough teaches oligonucleotides and related methods of performing amplification reactions whereby HIV nucleic acid sequences are being amplified and subsequently detected. Numerous primers are disclosed as well as sources for the genomic sequences and variances therebetween.

Research Genetics, through their advertisement, offers for sale software that permits the ordinary artisan to select primers based upon: (a) maximum and minimum lengths; (b) maximum and minimum melting temperatures; (c) variances in melting temperatures for primers; (d) maximum and minimum values for percent GC content; (e) product size; region from which the primers are to be selected; (f) selective elimination of primers with unwanted features; (g) on-

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screen depiction of target sequence as well as on-screen depiction of forward and reverse primers; and (h) a tabulation of identified primer pairs.

In view of the prior art of record, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have selected any number of primers that have a desired nucleotide sequence and which fall within a desired range in length as the target sequence was known and the capacity to select any sequence had been reduced to the level of design choice. In view of the profound impact that HIV has had on the human population, there would have been great motivation to develop useful primers and in view of the well developed nature of amplification reactions in general, and especially in the area of HIV, the ordinary artisan would have had a reasonable expectation of success.

Conclusion

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

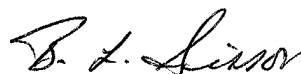
- a. US Patent 5,576,176 (Adams et al.) teach performing TR-PCR where primers anneal to a portion of the LTR of HIV.
- b. US Patent 6,001,558 (Backus et al.) teach detection of HIV-1 which includes the amplification of HIV sequences through the use of primers that can anneal to at least a portion of the LTR. Primers are disclosed.
- c. US Patent 6,025,124 (Adams et al.) teach amplification of HIV sequences through the use of primers that incorporate a marker. Primers anneal to a region of the LTR.

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8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradley L. Sisson whose telephone number is (703) 308-3978. The examiner can normally be reached on 6:30 a.m. to 5 p.m., Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W Gary Jones can be reached on (703) 308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3592 for regular communications and (703) 308-0294 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



Bradley L. Sisson
Primary Examiner
Art Unit 1655

BLS
July 17, 2000